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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,154	SKIFFINGTON ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,10,12,14,15,17-19,23,24,26 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4 and 30* is/are allowed.

6)☒ Claim(s) *1, 2, 5-7, 10, 12, 14, 15, 17-19, 23, 24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application (US Provisional Application No. 60/001,081, filed 12 July 1995) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 30 of this application. With respect to claim 30, the instant claim language of claims 30 recites that the unit dose reagent chamber is for detection of alkaline phosphatase (AP) in a test sample. The specific reagents recited include one selected from the group consisting of i) a detergent-containing buffered solution to release alkaline phosphatase (AP) from the test sample into solution and ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent. The disclosure of U.S. Provisional Application No. 60/001,081, filed 12 July 1995, discloses unit dose reagent chambers that include a cylinder having a one open end and an other opposite open end and a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment. Provisional Application 60/001,081 also discloses that i) a microbial lysis solution and ATP stabilizer can be a reagent held in the sealed chamber; ii) a buffer optimized for luciferin-luciferase reaction can be a reagent held in the sealed chamber; or iii) luciferin-luciferase reagent tablet can be a reagent held in the sealed chamber (See the first page of the disclosure and Figure 2). As a result, of all of the possible reagents listed in claim 30, U.S. Provisional Application 60/001,081 only provides support for "a luciferin-luciferase substrate reagent".

Note claims 1, 2, 4-7, 10, 12, 14, 15, 17-19, 23, 24 and 26 have benefit of the filing date of U.S. Provisional Application No. 60/007,585, filed 27 Nov. 1995, since these claims are supported by the disclosure of U.S. Provisional Application No. 60/007,585.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 5-7, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631).

The reference of Bernstein discloses a unit dose reagent chamber for use in a test apparatus (See Figure 4). The unit dose reagent chamber includes a cylinder with opposite open ends both of which are sealed by probe-puncturable membranes (6,7,8).

With respect to claim 1, while the reference of Bernstein discloses the use of reagent compositions within the unit dose chambers, the reference does not disclose the use of reagents specific for the detection of adenosine triphosphate wherein the reagent is either a detergent-containing buffered solution to release adenosine triphosphate from a test sample or a luciferin-luciferase reagent.

While the preferred embodiment of the reference of Bernstein is directed to the performance of an immunoassay detection, the reference discloses that the device is advantageous for assays that require multiple steps and require multiple reagents (See column 1, lines 13-28). The reference also discloses a number of types of reagents that can be used in the device including extraction reagent and lyophilized reagents (See column 3, lines 11-28).

The reference of Simpson et al. discloses a known method for the detection of adenosine triphosphate that employs a plurality of steps and reagents. The reagents include a detergent-containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent (See page 3, line 44, to page 4, line 15).

The reference of Rich et al. discloses that it is conventional in the art to provide reagents (92 and 94) for the detection of adenosine triphosphate in separate chambers that are separated by a frangible seal (82).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the adenosine triphosphate detection reagents as taught by the prior art references of Simpson et al. and Rich et al. within the test device structure as disclosed by the reference of Bernstein for the known and expected result of employing an alternative means recognized in the art for storing and performing a multiple step assay while providing the benefits disclosed by the reference of Bernstein when using the disclosed reagent holding system (See column 1, lines 4-28).

With respect to claim 2, the reference of Bernstein discloses the use of aluminum foil as a probe-puncturable membrane (See column 6, line 4).

With respect to claim 5, the combination of the references as discussed above would encompass the use of a unit dose chamber (15, 20, 27) in combination with a test apparatus (13) and a detergent-containing buffered solution to release adenosine triphosphate from a test sample and a luciferin-luciferase reagent.

With respect to claim 6, the test apparatus disclosed by the reference of Bernstein includes a longitudinally moveable probe (2,5) to puncture the membrane seals.

With respect to claim 7, the closed bottom end of the apparatus (13) of the reference of Bernstein is considered a test unit that includes one or more unit dose chambers.

With respect to claim 10, whether all of the reagents are positioned within the unit dose chambers or the last employed reagent is provided in the sealed bottom would have been obvious

to one of ordinary skill in the art for the known and expected result of providing an alternative means recognized in the art for providing reagents within a sealed chamber which are intended to be sequentially contacted with a probe member. Providing all of the reagents in a unit dose chamber would allow the tube and probe member to be manufactured independent of the specific reagents employed. However, it also would have been obvious to provide the last reagent in the sealed bottom to avoid the extra cost and materials associated with the use of an additional unit dose chamber.

With respect to claim 12, the reference of Simpson et al. discloses the additional use of a buffer or neutralizing solution (See page 3, lines 55-56) when detecting adenosine triphosphate that has been released from a cell sample using a detergent solution.

6. Claims 10, 14, 15, 17-19, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (US 4,770,853) in view of Simpson et al.(EP 0 309 184) and Rich et al.(US 3,666,631) taken further in view of Matsumoto et al.(JP 7-59555).

The combination of the references of Bernstein, Simpson et al. and Rich et al. has been discussed above.

Claims 10 and 14 differ by reciting that the device includes a longitudinal housing and a separate transparent test unit attached to one end of the housing that includes the unit dose chambers.

The reference of Bernstein discloses that that lower portion or test unit (10) can be integral or separable from the housing (13) (See column 4, lines 65-68).

The reference of Matsumoto et al. discloses a known swab sample device construction that includes housing (3) and a separate test unit (1) that includes unit dose chamber (2) for separating reagents (X and 5) (See Figures 1-4).

In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a swab sample and reagent contacting configuration as suggested by the reference of Matsumoto et al. for the known and expected result of providing an art recognized equivalent for contacting a swab sampler with a plurality reagents.

With respect to claim 15, the reference of Bernstein discloses the use of aluminum foil as a probe-puncturable membrane (See column 6, line 4).

With respect to claim 17, the test unit (1) suggested by the disclosure of Matsumoto et al. is detachably secured to one end of the test apparatus (3).

With respect to claims 18 and 23, while the reference discloses the use of a cover (6) for the test unit, instant claim 18 differs by reciting that the test unit is sealed with a probe-puncturable membrane.

The reference of Matsumoto et al. discloses that the use of a probe-puncturable membrane (2a, 2b) is known in the art for sealing a chamber.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to seal the open end of the test unit using an additional probe-puncturable membrane in place of cover (6) for the known and expected result of providing an alternative means recognized in the art for sealing a vessel. Use of the membrane would eliminate the need to remove cover (6) since probe device (4) would be capable of penetrating the membrane sealing the test unit.

With respect to claim 19, the reference of Simpson et al. discloses the additional use of a buffer or neutralizing solution (See page 3, lines 55-56) when detecting adenosine triphosphate that has been released from a cell sample using a detergent solution.

With respect to claims 24 and 26, the reference of Rich et al. discloses providing a luciferase/luciferin reagent in tablet form (94).

Allowable Subject Matter

7. Claims 4 and 30 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

Claims 4 and 30 would be allowable because the prior art of record fails to teach or fairly suggest the claimed ATP or AP testing device that includes pH indicator in combination with the claimed releasing solution, reaction stopping solution, or luciferin-luciferase or phosphatase substrate reagent to detect the ATP or AD of a test sample and wherein the pH indicator does not materially affect the basic characteristics of any of the above listed compositions.

Response to Amendment

9. The declaration under 37 CFR 1.132 filed 9/28/2005 is insufficient to overcome the rejection of claims 1, 2, 5-7, 10, 12, 14, 15, 17-19, 23, 24 and 26 based upon 35 USC 103 as set forth in the last Office action because:

The declaration merely provides opinion evidence. Note while a "declarant's opinion on the ultimate legal issue is not evidence in the case, some weight ought to be given to a

persuasively supported statement of one skilled in the art on what was not obvious to him". *In re Lindell*, 155 USPQ 521 (CCPA 1967). Also note "in assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the interest of the expert in the outcome in the case, and the presence or absence of factual support for the expert's opinion". Ashland Oil, Inc. v Delta Resins & Refractories, Inc. 227 USPQ 657 (Fed. Cir. 1985). In this case, the opinion evidence has been submitted to convey on the record that one of ordinary skill in the art would not have been motivated to modify the Bernstein apparatus for chemiluminescent detection of ATP because the modification would have made the apparatus of Bernstein unsuitable for its intended purpose of a solid phase immunodiffusion assay; the declarant is an employee of the assignee of the instant application and thus has an interest in the outcome of the application; and the declaration is devoid of any factual evidence supporting the statements within the declaration.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

10. With respect to the rejection of claims 1, 2, 5-7, 10 and 12 under 35 USC 103 over the combination of the references of Bernstein, Simpson et al. and Rich et al., Applicants argue that the preponderance of the evidence does not support the Examiner's conclusion of obviousness (See pages 2-10 of the response dated 9/28/05).

Applicants first argue that the Examiner has not taken all claim limitations into account. Applicants support this position by emphasizing that the Examiner has not established that the

reference of Bernstein discloses "a unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) in a test sample" as is required of the preamble of claim 1. Applicants stress that the disclosure of the reference of Bernstein is silent with respect to the use of the device for the detection of ATP and critical features of the device of Bernstein make it unsuitable for detection of ATP. Applicants conclude that the Examiner's reasoning that one skilled in the art would have been motivated to modify the Bernstein apparatus for any multi-step assay by placing any reagents into the vessels of Bernstein does not address the specific language of claim 1.

In response, the Examiner is of the position that all of the claim limitations of claim 1 have been taken into account and the rejection under 35 USC 103 does address the specific language of claim 1. First, the Examiner points to Figure 4 of the reference of Bernstein which discloses the cylinder and probe-puncturable membrane structures of claim 1 (See claim 1, paragraphs a) and b)). The Examiner then ascertains the differences between the prior art and the claimed invention by stating that while the reference of Bernstein discloses that a number of reagents can be contained within the chambers formed in the cylinder/membrane structure of Figure 4, the reference of Bernstein does not disclose the use of reagents specific for the detection of ATP. This statement clearly addresses the specific language of claim 1. Specifically, the reagent that is contained within the sealed compartment (See claim 1, paragraph c)) and would provide "a unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) in a test sample" (See the preamble of claim 1). To address the differences and establish what is known to one of ordinary skill in the art at the time the invention was made, the Examiner points to the broad disclosure of the reference of Bernstein

which discloses that "assays that require multiple steps, have multiple reagents, and have limited storage conditions are prone to misuse, especially if they are performed by individuals without adequate training or skills" (See column 1, lines 24-27). To address this problem, the reference of Bernstein provides the reagents within sealed compartments (See Figure 4) that are held within tube (Element 13 of Figure 3) so as to be sequentially contacted with a sample container swab (Elements 2, 5 of Figure 2). The reference of Bernstein conveys that "It is a particular object of the present invention to provide a test device that can be stored at nonrefrigerated temperatures, and can be utilized to perform an assay on a biological specimen or fluid without any additional reagents having to be provided to the test device" (See column 2, lines 61-66). The references of Simpson et al. and Rich et al. were cited by the Examiner to provide evidence that one of ordinary skill in the art recognizes that the detection of ATP involves a multiple steps and multiple reagents (See page 3, line 44, to page 4, line 15 of Simpson et al.) and that it is known in the art to provide the ATP detection reagents in separate compartments separated by a frangible seal (See Figure 3 of Rich et al.). In view of these disclosures, the Examiner concludes that one of ordinary skill in the art would be motivated to provide the reagents for the detection of ATP within a device with the construction of Bernstein for the known and expected result of providing a device that is recognized in the art for simplifying the performance of an assay that requires multiple steps and reagents while avoiding misuse and/or the adding of reagents and/or does not require refrigeration.

Next Applicants argue that the rejection should be withdrawn as lacking any rationale as to how or what would have suggested or motivated the skilled artisan to modify the Bernstein apparatus to provide the claimed invention. To support this position, Applicants stress that the

reference of Bernstein is directed to an apparatus for performing a solid phase immunodiffusion assay and modification of the reference of Bernstein as suggested by the Examiner would have made the apparatus of Bernstein unsuitable for its intended purpose of a solid phase immunodiffusion assay. Applicants stress that the ligand receptor reaction area (10) of the device of the reference of Bernstein is incompatible with the performance of chemiluminescent detection of ATP because the area has been designed to operate independently of instrumentation such as scintillation counters, flourometers and colorimeters and because the area is not closed and any solution would leak out the hole at the bottom of the test apparatus. In view of the specific structures of the ligand receptor reaction area (10) discussed above, Applicants stress that modification of the device as proposed by the Examiner would require substantial reconstruction and redesign of the device of Bernstein and the resulting device would then be unsatisfactory for its intended purpose.

In response, the Examiner is of the position that the prior art of record would have suggested or motivated the skilled artisan to modify the Bernstein apparatus to provide the claimed invention. First, while the preferred embodiment of the device of Bernstein is specific to immunodiffusion assays, one of ordinary skill in the art would have recognized that the disclosed teachings could be adapted for other assays that require multiple steps and multiple reagents as evidenced by the disclosure of Bernstein (See column 1, lines 24-27). Note "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 216 USPQ 1038 (Fed. Cir. 1983). In this case, one of ordinary skill in the art would recognize that the reference of Bernstein is concerned with at least two

separate problems, a first problem involving the performance of an assay that requires multiple steps with multiple reagents and a second problem involving visualization of an immunodiffusion assay. To address the first problem, the reference of Bernstein conveys to one of ordinary skill in the art that the combined structures shown in Figures 2, 3 and 4 allow an assay to be performed with multiple steps and multiple reagents. To address the second problem, the reference of Bernstein conveys to one of ordinary skill in the art a novel ligand receptor reaction area (10). When modifying the device as suggested by the rejection of record, the Examiner is of the position that one of ordinary skill in the art would have recognized that the ligand receptor reaction area (10) would not be required when adapting the device of Bernstein for chemiluminescent detection of ATP. As evidenced by the references of Simpson et al. and Rich et al., one of ordinary skill in the art would have recognized that the optical visualization chamber or area (10) would merely require a sealed chamber that could be optically interrogated. The Examiner is of the position that such a modification would not require substantial reconstruction and redesign of the device of Bernstein and the resulting device would not be unsatisfactory for its intended purpose of facilitating the performance of a multiple step and multiple reagent assay since this is a problem that is addressed by the disclosure of the reference of Bernstein.

Finally Applicants argue that the reference of Childs et al. (US 5,783,399) is evidence establishing secondary indicia of non-obviousness that others of ordinary skill in the relevant art arrived at alternative solutions. To support this position, Applicants reference *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977 (CAFC 1998). Applicants stress that the reference of Childs et al. establishes that there is at least a 50% likelihood that one skilled in

the art would have chose not to modify the Bernstein test apparatus. Applicants argue that despite having constructive possession of the cited references, when faced with the problem of using luciferin-luciferase to detect ATP on a test surface, the inventors of the Childs patent did not choose to modify the Bernstein reference but rather chose a completely different solution to that problem.

In response, the Examiner is of the position that the reference of Childs et al. fails to render the instant claims unobvious over the combination of the references of Berstein, Simpson and Rich. The fact that the reference of Childs et al. discloses a different device for performing a chemiluminescent detection of ATP is irrelevant in this application. Using Applicants' logic, any reference that is available as prior art and is different from an invention claimed in an application could be used to establish nonobviousness. Furthermore, it is not clear how the facts of *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* pertain to the instant rejection of the claims. It appears that in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* the prior art references taught away from the modification proposed by the Examiner. Specifically, the problem being solved in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* was hook breakage. The evidence of record established that those of ordinary skill in the art were experimenting with many different methods for reducing hook breakage and each of the references proposed a different solution. It was concluded, "this evidence creates a genuine issue as to whether those of ordinary skill would have had a motivation to combine needles with varying stem segment heights to form a trend". As a result, it is not clear how the facts presented in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* are germane to the instant

application. The reference of Childs et al. merely evidences that a different device is known in the art for performing chemiluminescent detection of ATP.

11. With respect to the rejection of claims 10, 14, 15, 17-19, 23, 24 and 26 under 35 USC 103 over the combination of the references of Bernstein, Simpson et al. and Rich et al. taken further in view of Matsumoto et al., Applicants argue that the preponderance of the evidence does not support the Examiner's conclusion of obviousness (See pages11 of the response dated 9/28/05). Specifically, Applicants argue that the reference of Childs et al. (US 5,783,399) is evidence establishing secondary indicia of non-obviousness that others of ordinary skill in the relevant art arrived at alternative solutions. To support this position, Applicants reference *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977 (CAFC 1998). Applicants stress that the reference of Childs et al. establishes that there is at least a 50% likelihood that one skilled in the art would have chose not to modify the Bernstein test apparatus. Applicants argue that despite having constructive possession of the cited references, when faced with the problem of using luciferin-luciferase to detect ATP on a test surface, the inventors of the Childs patent did not choose to modify the Bernstein reference but rather chose a completely different solution to that problem.

In response, the Examiner is of the position that the reference of Childs et al. fails to render the instant claims unobvious over the combination of the references of Berstein, Simpson and Rich. The fact that the reference of Childs et al. discloses a different device for performing a chemiluminescent detection of ATP is irrelevant in this application. Using Applicants' logic, any reference that is available as prior art and is different from an invention claimed in an

application could be used to establish nonobviousness. Furthermore, it is not clear how the facts of *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* pertain to the instant rejection of the claims. It appears that in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* the prior art references taught away from the modification proposed by the Examiner. Specifically, the problem being solved in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* was hook breakage. The evidence of record established that those of ordinary skill in the art were experimenting with many different methods for reducing hook breakage and each of the references proposed a different solution. It was concluded, "this evidence creates a genuine issue as to whether those of ordinary skill would have had a motivation to combine needles with varying stem segment heights to form a trend". As a result, it is not clear how the facts presented in *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH* are germane to the instant application. The reference of Childs et al. merely evidences that a different device is known in the art for performing chemiluminescent detection of ATP.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB